PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Study Protocol for an Open Trial of a Values and Acceptance-Based Intervention to Promote Adoption and Maintenance of Habitual Physical Activity Among Inactive Adults with Overweight/Obesity
AUTHORS	Lillis, Jason; Bond, Dale

VERSION 1 – REVIEW

REVIEWER	Courney Stevens, PhD Dartmouth-Hitchcock medical center, USA.
REVIEW RETURNED	01-Aug-2018

GENERAL COMMENTS	This protocol attempts to address a significant public health issue with an intervention model that could be employed as a stand alone intervention or adjunctive treatment. - Is the need for a highly skilled PhD level clinician a potential limitation of this study design re intervention scalability? - Are there plans to assess fidelity to the intervention manual? what about fidelity to the theoretical model in other forms of communication as well? - how many emails will be sent to each participant per week? is there a maximum amount? - the wording "never" on pg 5 line 21 is a bit too strong; research presented in symposium at the annual meeting of the society of behavioral medicine 2017 described the results of another brief ACT-based MVPA intervention that specifically targeted increases in SDT identified regulation. A manuscript reporting these results is currently elsewhere under review. - can the authors provide more rationale for the one time 4-hr workshop format (versus more typical behavioral health intervention lengths e.g., 5-12 sessions)? - why is BMI capped at an upper limit of 35? does this limit generalizability re this intervention as a weight loss program adjunct? - what is the rationale for setting the exercise goal to 200mins/week? is it 200 mins/week summed in bouts 10mins or more at a time? - How is this exercise goal first presented to participants and is there any way in which is conflicts with participants' self-identified goals? - typo on pg 7 linem 36, should "identify" be "identifying"?

REVIEWER	Margaret Schneider University of California, Irvine
REVIEW RETURNED	03-Sep-2018

GENERAL COMMENTS	The topic of this study is very timely, as ACT is newly being applied to the promotion of physical activity. The absence of a comparison group weakens the study design; a limitation that is noted in the

	manuscript. Using less than 150 minutes per week of MVPA as the criterion for entry into the study means that individuals who are very close to the cut-off will be eligible. It might be better to have a more stringent entry criterion so as to avoid including people who are close to meeting recommendations. This is a particular concern since the criterion spelled out in the power estimate for determining whether there is sufficient evidence of efficacy to justify further testing of the intervention is if the average MVPA at the end of the study is at least 150 minutes (page 10, line 29). Since it would be possible to enroll 48 persons with weekly MVPA at 140 minutes and then claim efficacy if the average MVPA reaches 150 minutes, there is a real concern about the eligibility criterion. Page 8, Line 36: "identify" should be "identifying" Page 9, line 12: the third question is rather vague and may be hard for participants to answer. Has this question been validate and/or pre-tested with the target population? Page 9, line 38: "assessment" should be "assessments" It is recommended that participants should be asked at each assessment period whether there is any reason that the 7-day actigraph assessment period was not representative of their usual level of activity (e.g., illness, vacation, etc). Page 9, line 56: insert the word "and" between "phone calls)," and "retention" Page 10, line 16: mis-spelling: "engages" Page 10, line 22: mis-spelling: "autonomy" Page 10, line 26: mis-spelling: "including" Page 10, line 33: should read "public health guidelines" The statistical analysis plan should include some mention of analyzing the data related to the processes being taught with ACT (i.e., those assessed via the SRQ-E and compACT).

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1 - Is the need for a highly skilled PhD level clinician a potential limitation of this study design re intervention scalability?	***The intervention is delivered by a Ph.D. level psychologist for two reasons: (1) This is a pilot study of a new intervention, and thus it is important to adequately test feasibility and acceptability without also asking additional empirical questions (e.g. Who can deliver the intervention effectively?) and, (2) The funding for this project was insufficient for hiring additional personnel. The intervention is not particularly complicated to deliver, there is no reason to assume so, and whether it needs a "highly skilled" clinician is an empirical question. As there is no reason to assume this as a limitation we have made no changes based on this feedback.***
- Are there plans to assess fidelity to the intervention manual? what about fidelity to the theoretical model in other forms of communication as well?	***Yes, there are plans to assess fidelity to the treatment protocol, we thank the reviewer for making a suggestion to include this information and apologize for the omission. Page 7 and 10 now include this information, 10% of sessions will be reviewed by a Ph.D.***

	level psychologist trained in both ACT and PA intervention delivery. There are no additional plans to assess fidelity.
- how many emails will be sent to each participant per week? is there a maximum amount?	***We have clarified the parameters on the emails on page 8. Participants receive weekly emails, one per week, for a total of 12 weeks, each containing a survey and a brief micro-intervention.***
- the wording "never" on pg 5 line 21 is a bit too strong; research presented in symposium at the annual meeting of the society of behavioral medicine 2017 described the results of another brief ACT-based MVPA intervention that specifically targeted increases in SDT identified regulation. A manuscript reporting these results is currently elsewhere under review.	***Although we were referring to using ACT to target autonomous motivation explicitly, not using SDT, we agree the language is strong and have removed said language in the current draft.***
- can the authors provide more rationale for the one time 4-hr workshop format (versus more typical behavioral health intervention lengths e.g., 5-12 sessions)?	***We have added one sentence of justification in the Intervention section on page 7.***
- why is BMI capped at an upper limit of 35? does this limit generalizability re this intervention as a weight loss program adjunct?	***In this case we made the decision to cap BMI at 35 because we have no weight altering component of our intervention, and it can be argued that individuals with BMI 35 and higher should be provided some measure of weight influencing skillstraining. As this is only an initial pilot study to gather feasibility data for a larger test of the model/intervention, we are unable to do this. This intervention had dual goals, (1) To be able to be utilized as a stand-alone, how it is tested here, and typically that would be with people who were lower on the BMI spectrum, and, (2) be used as an add-on to behavioral weight loss. Goal 2 was never going to be the first tested because we need to see if there is a signal in initial testing before adding it to a weight loss intervention, which requires far greater resources. We do not agree that this design decision limits generalizability in the way implied, but rather that the treatment validation process also includes eventually using it in the context of weight loss intervention with more broad BMI inclusion.***
- what is the rationale for setting the exercise goal to 200mins/week? is it 200 mins/week summed in bouts 10mins or more at a time?	***The rationale is stated in the Statistical Analysis, Sample Size, and Power Estimates section. Setting the program goal to 200 or more minutes per week, we believe, makes it more likely that we will achieve a mean of >150 minutes per week on the entire sample, given variability in response to treatment. We have nothing to add in terms of rationale. Also stated in the same section, all references to minutes of physical activity are "objectively measured bouted MVPA." The description in the Measurement of Bouted MVPA section states that the bouts are of at least 10 minutes. No changes were***

	made based on these comments.
- How is this exercise goal first presented to participants and is there any way in which is conflicts with participants' self-identified goals?	***The overall goal of the intervention (200 minutes) is not presented to the participants. It is the stated goal of the program with respect to our aims with the funding agency. As is such, we realize it is confusing to include it in the intervention section. We therefore have removed that sentence. The intervention section now only refers to the fact that participants generate their own PA goals.***
- typo on pg 7 linem 36, should "identify" be "identifying"?	***Thank you for catching the typo, we have corrected it.***
Reviewer: 2 - Using less than 150 minutes per week of MVPA as the criterion for entry into the study means that individuals who are very close to the cut-off will be eligible. It might be better to have a more stringent entry criterion so as toavoid including people who are close to meeting recommendations. This is a particular concern since the criterion spelled out in the power estimate for determining whether there is sufficient evidence of efficacy to justify further testing of the intervention is if the average MVPA at the end of the study is at least 150 minutes (page 10, line 29). Since it would be possible to enroll 48 persons with weekly MVPA at 140 minutes and then claim efficacy if the average MVPA reaches 150minutes, there is a real concern about the eligibility criterion.	***This criterion was used to obtain a sample comprised of participants who were all inactive according to public health guidelines but demonstrated a range of activity levels below this threshold. We have now recruited 2/3rd of the sample and in our phone screens the modal weekly MVPA was zero, and no potential participant was above 90 minutes, rendering the scenario described in the comment impossible and also rendering the potential for significant ceiling effects extremely unlikely. While we acknowledge the concern, the eligibility criteria was agreed upon with the funding agency and cannot be changed. Thankfully, the data have shown it will very likely not be a limiting factor.***
Page 9, line 12: the third question is rather vague and may be hard for participants to answer. Has this question been validate and/or pre-tested with the target population?	***It has not, but we feel this is not vague to participants who have completed the workshop intervention and have received values clarification and commitment intervention strategies. As we cannot change anything now we will note that there is a format for participants to provide open-ended feedback in regards to anything about their experience with the study on the Feasibility and Acceptability Form, and thus if this was a consistent problem, which we highly doubt, we at least have a mechanism to catch it.***
It is recommended that participants should be asked at each assessment period whether there is any reason that the 7-day actigraph assessment period was not representative of their usual level of activity (e.g., illness, vacation, etc).	***Thank you for the recommendation. We do indeed do that as part of our assessment protocol. We have added text to the document clarifying that on Page 10.***
The statistical analysis plan should include some mention of analyzing the data related to the processes being taught with ACT (i.e., those assessed via the SRQ-E andcompACT).	***We agree and have added as sentence clarifying that the GEE procedure previously described will also be used to examine CompACT and SRQ-E scores on Page 11.***
Page 8, Line 36: “identify” should be “identifying”	***We sincerely apologize for the number of***

Page 9, line 38: “assessment” should be “assessments” Page 9, line 56: insert the word “and” between “phone calls),” and “retention” Page 10, line 16: mis-spelling: “engages” Page 10, line 22: mis-spelling: “autonomy” Page 10, line 26: mis-spelling: “including” Page 10, line 33: should read “public health guidelines”	***typos and have corrected them. We thank the reviewer for their thorough documentation. We do note, however, that the “engages” mis-spelling is incorrect, that is meant to be “engage” as written, and thus no change is made for that one.***

VERSION 2 – REVIEW

REVIEWER	Courtney Stevens, PhD Dartmouth-Hitchcock Medical Center
REVIEW RETURNED	05-Nov-2018

GENERAL COMMENTS	Revisions are acceptable.